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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/648,078

08/26/2003

Terry L. Ray

4042-A4

3377

29370

7590

08/11/2006

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EXAMINER

ALI, SHUMAYA B

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/648,078	Applicant(s) RAY ET AL.	
	Examiner Shumaya B. Ali	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-14 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-14 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

In response to the office action mailed on 2/22/06 the Applicant has amended claim 1. Currently claims 1-14,17-20 are pending in the current application.

Response to Arguments

Applicant's arguments filed 5/25/06 with respect to claims 1,11, and 20 previously rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 14 of U.S. Patent No. 6,286,510B1 and claims 1,11, and 20 previously rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,6, and 11 of U.S. Patent No. 6,371,118B1 have been fully considered but they are not persuasive. Argument with respect to “the most profound difference is that the peripheral anchor is specifically for engaging the uterine tissue while the engagement element of patent ‘510 is specifically for engaging the oviduct. These are two very specific and different tissue in different areas requiring different structure to work” (see remark, page 10 lines 22-25 and page 11 lines 1-4), however claim 1 of the current application recites “Apparatus for preventing fluid transfer through an opening connecting an oviduct to a uterine cavity”, therefore the underline limitation is obvious over “engaging the oviduct” of US’510. Applicant argues for the same matter for US’118 (see remark page 11 lines 13-20). As stated above, apparatus of current application claims, “connecting an oviduct”. Therefore, nonstatutory obviousness-type double patenting with US Patent No.6, 371,118B1 and US Patent No. 6,286,510B1 is maintained.

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Applicant's argument with respect to "drawings and description show and describe a "barbed head 24". It is believed that a barbed head includes barbs and is adequately shown and described" (see remark page 9, lines 11-14) is not persuasive since as Applicant agrees claimed invention requires "barb", therefore drawing must show "barb" indicated with a reference number (see 37 CFR 1.83(a) which states the drawings must show every feature of the invention specified in the claims). For the above reasons drawing objection is maintained.

Applicant's argument with respect to the previously filed objection made to the specification is persuasive, therefore specification objection is withdrawn.

Applicant's arguments with respect to claim 1-4, 7-14, and 17- 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zeluff US Patent no. 5,954,715 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,11, and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 14 of U.S. Patent No.

6,286,510B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because limitations cited in claims 1,11, and 20 are recited in claims 1 and 14 of the published patent. Further, “an insert” of claims 1 and 14 reads on “body” and “an engagement element” reads on “a peripheral anchor” of claims 1,11, and 20 of the currently pending application. As to claim 20, the method steps would have been obvious with the use of device as recited in claims 1 and 14 of US’510B1.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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Claims 1,11, and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,6, and 11 of U.S. Patent No.

6,371,118B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because limitations cited in claims 1, 11, and 20 are recited in claims 1,6, and 11 of the published patent. Further, “an insert” of claims 1, 6, and 11 reads on “body” and “second portion” reads on “peripheral anchor” and “first portion” reads on “seal” of the currently pending application. As to claim 20, the method steps would have been obvious with the use of device as recited in claims 1,11 and 20 of US’118 B1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, and 12-14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 12 claim, “peripheral anchor portion comprises a plurality of spikes”, however Applicant may be referring multiple anchors being the “plurality of spikes”. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,7-9,11,17,18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zeluff US Patent no. 4,606,336

As to claim 1, Zeluff discloses an ostial occlusion device for preventing fluid transfer through an opening connecting an oviduct to a uterine cavity, wherein the apparatus comprising: a body (**fig.2, 12**) having a base (**bottom side of 12 which would be area defined by “D” in figure 2**) with a periphery (**fig.2, 14**); a seal (**22**) carried by the body for overlying and engaging uterine tissue leading to the opening and receiving fibroblast in-growth to create a hermetic seal between the oviduct and the uterine cavity (**col.3 lines 28-32**), a peripheral anchor portion (**20**) extending from the base (**see fig. 2**) for securing the body to the uterine tissue leading to the opening, the base overlying the opening (**col.5 lines 63-65**)

As to claim 7, Zeluff discloses wherein the body supports an engaging member (**fig.11, 58**) that may be grasp by a tool (**figures 5 and 6A, 26**) and which allows the apparatus to be manipulated during installation.

As to claim 8, Zeluff discloses wherein the engaging member is carried by an extension of the body (**see fig. 11**).

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As to claim 9, Zeluff discloses wherein the seal is formed of a biocompatible material that stimulates in-growth of fibroblastic tissue (col.3 lines 27-32 and 40-43, see claim 5 for “biocompatible”).

As to claim 11, Zeluff discloses claimed invention as applied for claim 1.

As to claim 17, Zeluff discloses claimed invention as applied for claim 7.

As to claim 18, Zeluff discloses claimed invention as applied for claim 8.

As to claim 20, Zeluff discloses structural limitation as applied for claim 1 required to perform the method steps cited in claim 20. Therefore, method steps would have resulted from using the apparatus of Zeluff.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2,10,12, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeluff US Patent no. 4,606,336

As to claims 2 and 12, Zeluff discloses claimed invention as applied to claim 1 except for wherein the peripheral anchor portion comprises a plurality of spikes extending from the base. Zeluff discloses peripheral anchor (20) being one spike for assist in maintaining the desired alignment between the body (“hub 12”) and uterotubal junction (see col.5, lines 63-65). However, at the time of the invention it would have been obvious to have one or multiple spike for the purposes of assist in maintaining the desired alignment between the body and uterotubal junction. Additionally, it would have been obvious to one of ordinary skill in the art that multiple peripheral anchors would have enhanced maintaining the desired alignment between the body and uterotubal junction.

As to claims 10 and 19, Zeluff discloses claimed invention as applied to claim 1 except for wherein the body is fabricated of a biodegradable material, however Applicant’s disclosure states, “body constructed rigid, non-porous, bio-compatible material such as stainless steel, titanium, ceramics poly-base material” (see page 8 lines 14-17). Zeluff discloses body fabricated from a rigid, non-porous material such as steel or radiopaque plastic (see col.4 lines 31-34), thereby the fabrication of the body as disclosed by Zeluff is considered within the scope of the claimed invention.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “barb” of claims 3 and 14 and “a

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tool” in claims 7 and 17 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

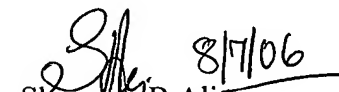
Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

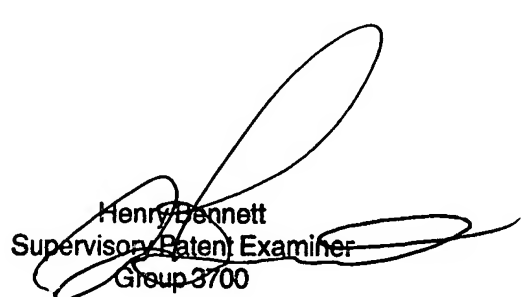
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-F 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shumaya B Ali
Examiner
Art Unit 3743


Henry Bennett
Supervisory Patent Examiner
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